Amendments to the Drawings:

Please replace originally-filed FIGS. 1-20 with formal versions of those figures found on the attached REPLACEMENT SHEETS.

REMARKS

A. Summary of Examiner Interview

Applicant thanks Examiner MacNeill for conducting a telephonic interview with Applicant's representative, Mark Garrett, and the inventor, Dr. Phillip Purdy, on October 2, 2007. The rejections of independent claims 1 and 67 were discussed. Applicant proposed amending claim 1 to recite advancing the device into the intracranial subarchnoid space, and the Examiner agreed such language would overcome the rejections. The Examiner asked about the feasibility of entering the subarachnoid space near the base of the skull, and Dr. Purdy explained that that no one skilled in the art would enter the subarachnoid space at such a location and then navigate to the intracranial subarachnoid, due to the high risk of injury involved. The Examiner suggested that Applicant consider US 4,904,237 and US 6,379,331. Applicant discussed amending claim 67 in the same fashion as claim 1.

B. Claims 1, 7, 11, 13, 24, 27, and 28 Are Novel over Harper

Claims 1, 7, 11, 13, 24, 27, and 28 stand rejected as anticipated over US 6,436,091 (Harper). Claim 21 was listed as being rejected (p. 2) but was not specifically discussed and was listed as being allowable (p. 5). The Examiner agreed that the claim was allowable in the interview discussed above.

Claim 1 has been amended to recite "advancing the device over the guidewire from the spinal subarachnoid space into the intracranial subarachnoid space," which Harper neither teaches nor suggests. For this reason, the rejection is overcome and should be withdrawn.

C. The Obviousness Rejection of Claims 2 and 22 Is Overcome

Claims 2 and 22 stand rejected as being obvious over Harper in view of US 6,328,694 to Michaeli. Claims 2 and 22 depend from claim 1 and are novel over Harper for at least the same

reason as claim 1. Michaeli does not cure Harper's deficiency. Therefore, claims 2 and 22 are nonobvious over the asserted combination, and the rejection should be withdrawn. Furthermore, Michaeli fails to disclose or suggest creating a lesion in the brain, as recited in claim 22. The Office does not address this limitation. Thus, claim 22 is patentable over the asserted combination for this additional reason.

D. The Obviousness Rejection of Claim 3 Is Overcome

Claim 3 stands rejected as being obvious over Harper. The rejection is overcome and should be withdrawn for the same reason as the rejection of independent claim 1 based on Harper.

E. The Obviousness Rejection of Claims 8 and 24 Is Overcome

Claims 8 and 24 stand rejected as being obvious over Harper in view of US 6,004,262 to Putz. Both claims depend from claim 1 and are novel over Harper for at least the same reason as claim 1. Putz does not cure Harper's deficiency. Therefore, both claims are nonobvious over the asserted combination, and the rejection should be withdrawn.

F. The Obviousness Rejection of Claims 25, 26, and 67 Is Overcome

1. Claims 25 and 26

Claims 25 and 26 stand rejected as being obvious over Harper in view of US 6,330,466 to Hofmann. Claims 25 and 26 depend from claim 1 and are novel over Harper for at least the same reason as claim 1. Hofmann does not cure Harper's deficiency. Therefore, claims 25 and 26 are nonobvious over the asserted combination, and the rejection should be withdrawn.

2. Claim 67

Independent claim 67 stands rejected as being obvious over Harper in view of Hofmann. Claim 67 has been amended to recite "advancing the device over the guidewire from the spinal

subarachnoid space into the intracranial subarachnoid space," which Harper neither teaches nor suggests. Hofmann does not cure Harper's deficiency. Therefore, claim 67 is nonobvious over the asserted combination, and the rejection should be withdrawn.

G. Claims 4-6, 12, 17-21, and 23 Have Been Rewritten

Claims 4-6, 12, 17-21, and 23 have been objected to as being dependent on a rejected base claim, but would be allowable if rewritten into independent form. Applicant has done this by rewriting: (a) claims 4-6, 12, and 17-20 using the claim language of independent claim 1 found in the March 7, 2007 response, which was found allowable in the March 26, 2007 final Office Action; (b) claim 21 using the claim language of independent claim 1 from the last response (June 19, 2007), which was found allowable in the outstanding Office Action; and (c) claim 23 using the claim language of independent claim 1 from the October 2, 2006 response, which was found allowable in the November 7, 2006 Office Action.

H. Response to the Examiner's Questions

During the October 2, 2007 telephone interview, the Examiner asked whether it was possible to navigate from the spinal subarachnoid space after entry near the base of the skull into the intracranial subarachnoid space. Dr. Purdy explains in his declaration that it is not:

> [It is not] due to the severe risk of injury involved. The limitation in development of medical procedures relating to navigation into the intracranial subarachnoid space from a cervical insertion has been that the spinal cord occupies the subarachnoid space throughout the cervical spine. The only approach that has been developed to that space has been posteriorly between the first and second cervical vertebrae, where there is a small space approximately 2-3 mm in width separating the spinal cord from the posterior margin of the spinal subarachnoid space. To approach that space, one must insert a needle perpendicularly from a lateral approach. This is the approach that is used for cervical myelography and for withdrawal of CSF using a "cervical puncture" technique, and I have used that approach many times in my practice. However, in order to then navigate the subarachnoid space from that approach, it would be necessary to make an abrupt 90-degree turn either cephalad or caudad within the canal, and in order to navigate to the more significant structures in the posterior fossa (the cranial nerves,

> arteries, and brainstem), one would have to encircle the spinal cord while making that 90-degree turn. The mechanics of this move are such that extreme risk of injury to the spinal cord, blood vessels, or lower cranial nerves would ensue. Hence, this approach would be unworkable from a patient risk standpoint.

Purdy Decl. at para. 4.

During the interview, the Examiner suggested that US 4,904,237 (Janese) might be relevant to the claims in terms of intracranial access. Dr. Purdy explains in his declaration that Janese fails to disclose or suggest advancement from the spinal subarachnoid space to the intracranial subarachnoid space:

> I have reviewed the Janese patent, and find no discussion or suggestion of advancement from the spinal subarachnoid space into the intracranial subarachnoid space. The focus of the patent is the computerized fluid exchange apparatus. Janese explains that the apparatus can be used to remove CSF through a catheter inserted in the subarachnoid space; the apparatus then treats and returns the CSF to the subarachnoid space. Janese states that the apparatus "provides prophylaxis against symptomatic intra-cranial arterial spasm by removing blood and blood byproducts from the cerebrospinal fluid and by cooling the circulated cerebrospinal fluid and by cooling the circulating cerebrospinal fluid to improve injured brain survival." Col. 2. Janese also states that his apparatus can be used to treat intracranial arterial vasospasm, brain trauma, and fetal intracranial hemorrhage. Col. 10. However, nothing in the patent discusses or suggests navigation into the intracranial subarachnoid space to accomplish any of those suggested treatments. For example, Janese does not provide any information about monitoring the location of the catheter within the subarachnoid space. Additionally, Janese describes allowing a patient to rest on her side after the catheter is placed, which indicates that Janese does not contemplate or suggest intracranial navigation. A patient undergoing such navigation would be much more likely to be prone during that procedure.

Purdy Decl. at para. 5.

During the interview, the Examiner also suggested that US 6,379,331 (Barbut) might be relevant to the claims. Barbut teaches away from navigating from the spinal subarachnoid space to the intracranial subarachnoid space. Dr. Purdy explains why in his declaration:

> Barbut illustrates an embodiment in which the catheter is inserted at the C6-C7 interspace. However, there is no safe insertion point for a catheter at C6-C7 because the spinal cord is immediately adjacent to the dura at that location. In fact, the spinal cord actually widens in the lower cervical spine to occupy more of

the subarachnoid space due to the extensive innervation to the upper extremities that exit at that location. Furthermore, Barbut discloses cranial access for CSF exchange through a burr hole in the skull, which shows Barbut did not consider it reasonable to navigate from the spinal subarachnoid space into the intracranial subarachnoid space.

Purdy Decl. at para. 6.

I. Conclusion

The pending claims are in condition for allowance. The Examiner is invited to contact the undersigned attorney at (512) 536-3031 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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